

S/N 10/603,876

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Paul V. Goode Jr.	Examiner:	Lenwood Faulcon
Serial No.:	10/603,876	Group Art Unit:	3762
Filed:	June 25, 2003	Docket:	279.A84US1
Title:	METHOD AND APPARATUS FOR TRENDING A PHYSIOLOGICAL CARDIAC PARAMETER		

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Applicant requests pre-appeal review. No amendments are being filed with this request, which is being filed with a Notice of Appeal.

*§103 Rejection of the Claims*

1. Claims 1, 3, 8-14, 17, 19, 29 and 43 were rejected under 35 U.S.C. § 103(a) over Levine et al. (U.S. Patent No. 6,058,328) in view of Chirife (U.S Patent No. 5,154,171).

*Concerning claims 1, 3, 8-14, 17, 19:*

These references do not show using a trended ejection fraction to predict the onset of a sudden cardiac death episode. Although Levine preempts a tachyarrhythmia, the Final Office Action admits it does not use ejection fraction. While Chirife uses ejection fraction, it does so only for controlling pacing rate in bradycardia patients who have too-slow heart rhythms and need a pacemaker. (See, e.g., Chirife at Abstract, and at col. 3, lines 48-57.) Chirife and Levine fail to indicate that ejection fraction can be used to predict the onset of a sudden cardiac death episode using trended data, as claimed. Moreover, Chirife relates to bradycardia patients with too slow heart rhythms, and Levine relates to tachycardia patients with too fast heart rhythms. Because Chirife and Levine directly teach away from each other, they lack the required motivation to combine. Because using a trended ejection fraction to predict the onset of a sudden cardiac death episode is not shown in either reference, and because there is no motivation in the references for their combination, and because the references directly teach away from each other, no proper *prima facie* case of obviousness exists with respect to these claims.

Concerning claims 30 and 32:

These references do not show monitoring, using the intra-cardiac impedance trend data, a drug regimen or progress of congestive heart failure. The Advisory Action cites the following portion of the March 22, 2006 Office Action:

In regards to claims 30, 32, 46 and 48, Examiner takes the position that although Levine et al. does not specifically teach of monitoring for a drug regimen or congestive heart failure, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Levine et al. to include the detection of various cardiac conditions, since this would enhance the system's ability and accuracy in predicting and treating sudden cardiac death, as suggested by Levine in the teaching of monitoring for various cardiac conditions that inherently may effect blood flow (col. 33, lines 13-21.)

(March 22, 2006 Office Action at 3.) The Office Action admits that monitoring a drug regimen or progress of congestive heart failure is not present in the references. Moreover, the only portion of either references cited in support for this wholly conclusory assertion merely states:

Thus, a marker for ischemia, such as the high frequency cardiac activity signals herein described, when identified, may be used in accordance with the invention to trigger a change in the pacemaker's behavior to either modify the AV delay or slow the heart rate (assuming atrial or AV pacing) in an effort to reduce ischemia and hence, prevent arrhythmias as well as some of the other dire consequences of myocardial ischemia such as a myocardial infarction (heart attack).

(Levine at col. 33, lines 13-21.) This passage falls far short of suggestion of monitoring, using the intra-cardiac impedance trend data, "a drug regimen" or "progress of congestive heart failure," as claimed. In fact, this passage actually teaches away from using intra-cardiac impedance data because it relates to using high frequency cardiac activity signals (e.g., electrogram signals) instead of the intra-cardiac impedance data. Because all elements of claims 30 and 32 are not present in the cited portions of the cited references, Applicant respectfully submits that no *prima facie* case of obviousness exists with respect to these claims.

Concerning claims 31 and 47:

The references do not show monitoring a trend of intracardiac impedance for detecting myocardial infarction. While Levine apparently discloses *preventing* a myocardial infarction (see Levine at col. 33 lines 19-21), it does not show monitoring for a myocardial infarction, much less so monitoring using intracardiac impedance instead of using "a high frequency cardiac activity

signal," as in the cited passage (see Levine at col. 33, lines 13-21.) Because all elements of claims 31 and 47 are apparently not present in the cited portions of the cited references, Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims.

2. Claims 5, 7, 24-27, 30-42, 44 and 46-49 were rejected under 35 U.S.C. § 103(a) over Levine et al. (U.S. Patent No. 6,058,328).

*Concerning claims 5 and 7:*

The Final Office Action states:

Examiner takes the position that Levine et al. inherently teaches of the ability for detecting the difference between resting and non-resting parameters to predict the onset of a sudden cardiac death episode (col. 29 lines 41-48 and claim 46).

(Office Action ¶4.) However, the cited portion of Levine merely pertains to detecting resting and non-resting heart rate—which is not derived from intra-cardiac impedance, as claimed, but which is instead derived from detecting intrinsic electrical heart signals. (See Levine at col. 7, lines 38-45; col. 8, lines 49-56.) Therefore, the Office Action ignores the language in claim 5 of deriving the physiologic cardiac parameter from intra-cardiac impedance. The Advisory Action states:

In regards to claims 5 and 7, Examiner maintains the position that the system as taught by Levine et al. is inherently capable of detecting intra-cardiac impedance when the patient is at rest or when the patient is not at rest. Examiner takes the position that even if the Levine et al. reference is discussing resting and non-resting states in the context of electrical events, the system is still capable of monitoring intra-cardiac impedance during such states. Further, Applicant's claim 5 is merely claiming the ability to measure intra-cardiac impedance during a time in which the patient is at rest or is not at rest.

(Advisory Action at 3.) Applicant respectfully disagrees. The Office Action has not established a *prima facie* case of inherency because, as recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," citing Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Nothing in Levine implies that its devices necessarily measures intra-cardiac impedance during resting and non-resting states. Moreover, Applicant's claim 5 does not, as asserted, "merely [claim] the ability to measure intra-cardiac impedance

during a time in which the patient is at rest or is not at rest,” instead, claim 5 actually recites detecting a difference between an impedance-derived parameter at rest and the impedance-derived parameter when not at rest, and predicting the onset of a sudden cardiac death episode using this difference. Levine fails to expressly or inherently disclose, teach, or suggest this. Because all elements of claims 5 and 7 are not expressly or inherently (e.g., “necessarily”) disclosed, taught, or suggested by Levine, Applicant respectfully submits that no *prima facie* case of obviousness exists with respect these claims.

Concerning claims 24-27, 30-42, 44 and 46-49:

The Office Action states:

Levine et al. also teaches of detecting the occurrence of a myocardial infarction and other cardiac conditions that affect a heart’s blood flow (col. 33 lines 13-21). In regards to claims 30, 32, 46, and 48, Examiner takes the position that although Levine et al. does not specifically teach of monitoring for a drug regimen or congestive heart failure, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Levine et al. to include the detection of various cardiac conditions, since this would enhance the system’s ability and accuracy in predicting and treating sudden cardiac death, as suggested by Levine et al. in the teaching of monitoring for various cardiac conditions that inherently may effect blood flow (col. 33 lines 13-21).

(Office Action ¶ 4.) However, the cited portion of Levine apparently merely pertain to monitoring intrinsic cardiac activity signals—not a parameter derived from intracardiac impedance, as recited or incorporated in claims 24-27, 30-42, 44 and 46-49. Therefore, the Office Action appears to be improperly ignoring the language in these claims by which the physiologic cardiac parameter is derived from intra-cardiac impedance. The Advisory Action states:

In regards to claims 24-27, 30-42, 44 and 46-49, Examiner maintains the position that the Levine et al. reference teaches that physiologic cardiac parameters can be derived from intra-cardiac impedance (see for example col. 28 lines 38-51).

(Advisory Action at 3.) However, the cited portion of Levine merely pertains to preemptive tachyarrhythmia pacing using sensed parameters—not to monitoring a drug regimen, a progress of congestive heart failure, or whether a myocardial infarction has occurred as similarly recited or incorporated in the present claims, as discussed in detail above (for example, the preventing a myocardial infarction in Levine has nothing to do with actually detecting or monitoring a

myocardial infarction, as discussed above.) In sum, because all elements of these claims are apparently not present in Levine, Applicant respectfully submits that no *prima facie* case of obviousness exists with respect to these claims.

3. Claims 15 and 18 were rejected under 35 U.S.C. § 103(a) over Levine et al. (U.S. Patent No. 6,058,328) in view of Chirife (U.S Patent No. 5,154,171) as applied to claims 1-3, 8-14, 17, 19, 29 and 43 above, and further in view of Causey et al. (U.S. Patent No. 4,809,697). Applicant respectfully traverses on the grounds discussed above with respect to the § 103 rejection of their base claim 8 using Levine and Chirife.

4. Claims 20-23 were rejected under 35 U.S.C. § 103(a) over Levine et al. (U.S. Patent No. 6,058,328) in view of Chirife (U.S Patent No. 5,154,171) as applied to claims 1-3, 8-14, 17, 19, 29 and 43 above, and further in view of Koestner et al. (U.S. Patent No. 5,300,093). Applicant respectfully traverses on the grounds discussed above with respect to the § 103 rejection of their base claim 8 using Levine and Chirife.

Applicant respectfully requests reconsideration and withdrawal of all rejections. The Examiner is invited to telephone the below-signed attorney at (612) 373-6951 to discuss any questions which may remain with respect to the present application. If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

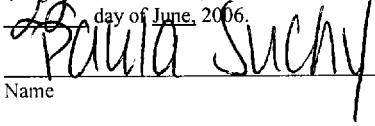
Respectfully submitted,

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Date June 22, 2006 By   
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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this day of June, 2006.

  
Name

  
Signature